

## REMARKS

### **Formal Matters**

Claims 1-22 are pending.

Claims 1-22 were examined and rejected.

Claims 1, 7, 13, and 19 have been amended. Support for these amendments is found in the claims as originally filed, as well as in the specification at, for example page 14, lines 22-29.

The Applicant respectfully requests reconsideration of the application in view of the remarks made herein.

No new matter has been added.

### **Rejections under 35 U.S.C. § 102(e)**

Claims 1-12 have been rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,534,294 to Lee et al. (hereinafter Lee). This rejection is respectfully traversed.

The claimed invention is directed to a method of detecting the presence of an analyte in a sample by first combining the sample with at least two derivatizing agents to form derivatives of the analyte. The resulting product is then subjected to chromatographic separation. Using the resultant retention times and ratios of the derivatives, the presence of the analyte in the sample is then detected.

In contrast, Lee discloses subjecting a compound to a single derivatizing agent and then using the peak retention times and peak area ratios of the resultant chromatograms to determine the identity of the compound. The Office Action notes that, Lee used gas chromatography to identify glucose based on the peak retention times and peak area ratios of  $\alpha$  and  $\beta$  anomers. However, unlike the present invention, Lee does not teach the use of **two different** derivatizing agents to produce two different derivatives of the same analyte. The disclosure in Lee is limited to using one derivatizing agent, i.e., TMS (see Column 9, lines 17-39).

Without conceding to the correctness of this rejection, Claims 1 and 7 have been amended to further specify **“combining said sample with at least two derivatizing agents”** As mentioned above, support for these amendments is found in the claims as originally filed, as well as in the specification at, for example page 14, lines 22-29.

It is well established that “[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” Verdegaal Bros. v. Union Oil Co. of California, 2 USPQ 2d 1051, 1053 (Fed. Cir. 1987), cert. denied, 481 U.S. 1052 (1987). See also, Scripps Clinic and Research Foundation v. Genentech, Inc., 18 USPQ 2d 1001 (Fed. Cir. 1991).

Since the disclosed method of Lee requires exposing the analyte to only one derivatizing agent instead of exposing the analyte to two derivatizing agents, as recited in the amended claims, Lee fails to disclose each and every element of the claimed invention.

Accordingly, the Applicant submits that the rejection of Claims 1-12 under 35 U.S.C. §102(e) has been adequately addressed in view of the amendments to the claims and remarks set forth above. Therefore, the Examiner is respectfully requested to withdraw the rejection and allow the application to proceed to issue.

### **Rejections under 35 U.S.C. § 103**

The Office Action rejects Claims 1-22 under 35 U.S.C. § 103 as being unpatentable over U.S. Patent No. 4,990,458 to Rosenfeld et al. (hereinafter Rosenfeld) (see e.g., Office Action page 3). However, the Office Action also rejects Claims 1-22 under 35 U.S.C. § 103 as being unpatentable over U.S. Patent No. 5,952,336 to Cook et al. (hereinafter Cook) (see e.g., Office Action page 4). It is assumed by the Applicants that the rejection of Claims 1-22 under 35 U.S.C. § 103 is

based on the combination of both references. Accordingly, this response addresses both references as such.

As previously noted, the presently claimed invention is directed to a method of detecting the presence of an analyte in a sample by first combining the sample with at least two derivatizing agents to form derivatives of the analyte, subjecting the combination of derivatives to chromatographic separation, and using the retention times and ratios of the derivatives to detect the presence of the analyte in the sample.

The law is clear that to establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. In re Fine, 5 USPQ2d 1596 (Fed. Cir. 1988); In re Jones, 21 USPQ2d 1941 (Fed. Cir. 1992). Second, there must be a reasonable expectation of success. In re Merck & Co., Inc., 231 USPQ 375 (Fed. Cir. 1986). Finally, the prior art reference, or references when combined, must teach or suggest all the claim limitations. In re Royka, 180 USPQ 580 (CCPA 1974).

The Office Action first cites Rosenfeld as teaching a method of analyzing prostaglandin E2 (PGE2) using PFBBR and PFBHOX derivatizing agents. However, as noted in the Office Action, **Rosenfeld fails to teach or even suggest a method where the ratio and retention time of two or more different derivatives are used to detect the presence of a single analyte.** In fact, Rosenfeld does not even teach or suggest determining the ratio of two different derivatives of the same analyte, much less using this value along with retention times to detect the presence of the analyte.

It is assumed by the Applicant the Office Action cites Cook as making up the noted deficiency in Rosenfeld. Specifically, the Office Action states that Cook teaches that similar compounds can be used as internal standards for each other in

chromatographic analyses, and that the area ratios of two similar compounds can be used to quantify for the compounds. In addition, the Office Action also states that it would have been obvious to use peak ratios of the similar compounds to identify and/or quantify the similar compounds as taught by Cook.

However, Cook teaches measuring areas of the chromatographic peaks associated with a **single** derivative from **two different analytes** and comparing the area ratios of the test derivatives to the area ratios of known amounts of those test derivatives subjected to the same conditions, thereby enabling one to determine the different analytes in a sample (see Column 10, lines 33-37). Therefore, **Cook, like Rosenfeld, also fails not teach using the area ratios and retention times of two or more derivatives of the same analyte to determine the presence of the analyte in a sample.** Furthermore, Cook also does not teach subjecting a single analyte to two or more different derivatizing agents. The disclosure in Cook is limited to using two different analytes, subjecting the two analytes to chromatographic separation, and determining the concentration of the two different analytes in the sample based on comparing the area ratios and peaks of the analytes in the sample to known area ratios and peaks (see Column 10, lines 42-50).

Therefore, both Rosenfeld and Cook either taken alone or in any combination, both fail to teach **using the area ratios and retention times of two or more derivatives of the same analyte to determine the presence of the analyte in a sample.** Such is simply not shown. Since the cited references fail to teach all the elements of the rejected claims, the cited references, taken alone or in any combination, fail to render the claimed invention obvious.

As such, Claims 1-22 are not rendered obvious under 35 U.S.C. § 103. Therefore, the Applicant respectfully requests that this rejection be withdrawn.

### CONCLUSION

Applicants submit that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-1078.

Respectfully submitted,  
BOZICEVIC, FIELD & FRANCIS LLP

Date: 3.3.04

By:   
Bret Field  
Registration No. 37,620